

Quick Look:

This document includes:

Background Information ,
FAQs, Quick Facts and Links to
More Information about <u>HB</u>
7095 sponsored by the <u>Health</u>
& Human Services Committee,
Chaired by <u>Representative</u>
Schenck.

Quick Facts:

Number of practitioners authorized to dispense oxycodone:

Florida –156 **(11%)** Rest of Nation – 1,423

Grams of oxycodone sold by practitioners:

Florida –111,934 **(85.3%)** Rest of Nation – 131,249

Number of practitioners authorized to dispense methadone:

Florida –55 **(49.5%)** Rest of Nation – 111

Grams of methadone sold by practitioners:

Florida –47,515 **(93.1%)** Rest of Nation – 51,046

OPI Pulse: Distribution of Controlled Substances

Background:

Since the 1990s the legal use of prescription drugs has increased dramatically in Florida and around the nation. While these medications are valuable for the treatment of chronic pain, their use comes with unavoidable risks including serious complications like misuse, abuse, addiction, overdose and death.

Prescription pain relievers in Florida can be lawfully dispensed in a number of ways. Pharmacies undergo a formal permitting process as outlined in law to dispense medication. Physicians must be licensed by the state, have a federal Drug Enforcement Administration (DEA) number, and must register with the Florida Department of Health (DOH) in order to dispense. Pain management clinics, which are facilities employing physicians specializing in the treatment of pain, are also required to register with the Florida DOH.

The Florida Department of Health regulates the dispensing of all prescription drugs in the state. Regulators from DOH rely on assistance from local and state law enforcement entities and public complaints to identify and regulate the unlawful distribution, prescribing and dispensing of pain relievers such as oxycodone, methadone, hydromorphone and hyrdocodone.

Issues at a Glance:

Advocates of a ban on practitioner dispensing of controlled substances cite the primary source of Florida's prescription drug abuse problem as disreputable medical professionals dispensing medically unjustifiable amounts of controlled substances to addicts and people who will sell the drugs on the street. Advocates also assert these medical practitioners make a quick profit by prescribing and dispensing highly addictive drugs to patients with whom they often have no ongoing clinical relationship and to whom they provide no general medical care. Proponents of limiting controlled substance dispensing by physicians reference the following information as reasons to propose the legislation:

- According to the DEA, of the 50 practitioners who dispensed the most oxycodone in the country in 2008-09, 49 of them were in Florida, and half were located in Broward County.
- Data submitted in 2006 to the Department of Justice (DOJ) by drug distributors show that, while Florida's residents represent 5.4 percent of the nation's population, the state is home to 11 percent of the nation's practitioners who buy oxycodone to dispense and

PUBLIC INFORMATION

Terms to Understand:

Controlled Substance:

 A drug which has been declared by federal or state law to be illegal for sale or use, but may be dispensed under a prescription from an authorized practitioner.

Dispense:

 The transfer of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer.

Prescribe:

 To order drugs by written and signed forms, or direct verbal communication by a licensed practitioner to another person authorized to dispense.

Administer:

 To manage the use of a certain medication or substance by directly administering an appropriate dose to a patient.

- 49.5 percent of the nation's practitioners who buy methadone to dispense.
- The same DOJ data showed that Florida practitioners are responsible for 85.3 percent of the nation's oxycodone dispensed by practitioners.
- The same DOJ data also showed that Florida practitioners are responsible for 93.1 percent of the nation's methadone dispensed by practitioners.

What the Bill Does:

House Bill 7095 was introduced by the Health & Human Services Committee on March 10, 2011. The bill was reported favorably and next heard in the Judiciary Committee on March 30, 2011. Among other things, the bill proposes to ban the dispensing of Schedule II and III controlled substances by practitioners. House Bill 7095 was amended to address several issues relating to prescribers, dispensers and distributers of controlled substances including pharmacies. In addition, the bill addresses issues related to the Department of Health, law enforcement, criminal penalties, the Prescription Drug Monitoring Program, and funding. The bill as amended was reported favorably by the House Appropriations Committee on April 12, 2011, and was amended further upon Second Reading on the House floor. The bill was passed by the Florida House of Representatives by a vote of 116-1 on Thursday, April 21, 2011. The bill as amended would:

Dispensing:

- Make it illegal for doctors to dispense Schedule II and III controlled substances. Instead, patients would fill their prescriptions in a pharmacy.
- Provide criminal penalties and grounds for disciplinary action against those who continue to dispense illegally.
- Provide an exception for dispensing within seven days after surgery.

Prescribing:

- Require the registration of practitioners prescribing controlled substances with the DOH.
- Require doctors to use tamper proof prescription pads purchased from an approved vendor. The supply of prescription pads would be limited and vendors would be required to report the purchase of these prescription pads to the DOH.
- Enact standards of care for all physicians prescribing controlled substances for the treatment of chronic pain.

Distribution:

PUBLIC INFORMATION

Links to More Information:

National Drug Intelligence
Center

Centers for Disease
Control - Prescription &
Over-the-Counter Drug
Abuse

<u>Prescription Drug</u> <u>Monitoring Program in</u> Florida

- Buy back the controlled substances within an authorized period from practitioners who are no longer permitted to dispense them.
- Provide an exemption from pedigree paper requirements to allow distributors to resell the drugs.
- Report the distribution of controlled substances listed in Schedules II, III, IV and V in Florida.
- Credential physicians and pharmacies that purchase Schedule II or III controlled substances. The credentials must include:
 - Determination of the clinical nature of the entity purchasing Schedule II or III controlled substances;
 - Review of the entity receiving the controlled substances history of purchases of Schedule II or III controlled substances;
 - Determination that purchasing history of such an entity is consistent with and reasonable for that entity's clinical business needs; and
 - Level Two background screening of any person who owns, manages, oversees or controls the operation of the entity purchasing controlled substances. This includes officers and members of the board of directors of an entity that is a corporation.
- Prohibit the distribution of more than 5,000 unit doses of specific drugs to a retail pharmacy in any given month. The specific drugs are: oxycodone, hydropmorphone, hydrocodone, methadone, any benzodiazepine, or their derivatives.
- Require distributers to investigate suspicious transactions, including those involving more than 5,000 unit doses of controlled substances in any given month.
- Establish grounds for disciplinary action, including loss of distributing permit, for failure to comply with the points listed above.

Pharmacies

- Require pharmacies to be permitted through the DOH. Permitting requirements include:
 - Mandatory on-site inspections of pharmacies;
 - Disclosure of financial interests;
 - Prohibition of a physician owning a pharmacy;
 - Increased compliance requirements, for which a designated pharmacy manager is responsible; and
 - Specific grounds for denial of permits including criminal history and prior non-compliance with specific regulations.
- Require that community pharmacies may not dispense a controlled substance listed in Schedule II or III unless the pharmacy obtains a permit under the new standards.

OFFICE OF PUBLIC **INFORMATION**

Additional Resources:

Florida House of Representatives

Florida Department of Law Enforcement

Florida Department of Health

Florida Attorney General

Require pharmacies dispensing controlled substances to maintain a log of all prescriptions filled and make this log available to the Department of Health or the Florida Department of Law Enforcement (FDLE) upon request.

The Department of Health

- Require that the DOH actively monitor the purchasing from wholesalers to identify patterns that are inconsistent with the purchasing entity's clinical needs.
- Require that the DOH must actively monitor practitioner purchases of approved tamper proof prescription pads.
- Require that the DOH must report suspicious purchases to FDLE for coordination with local law enforcement.
- Require the DOH declare a public health emergency regarding the prescribing and dispensing of controlled substances immediately after the bill becomes law in order to authorize specific actions for high risk practitioners such as law enforcement seizing medications from pain clinics.

Pain Clinic Regulations

- Maintain the requirement for the registration of pain clinics until 2016 at which time the regulations would sunset.
- Enact specific provisions of the Board of Medicine's proposed clinic rules into law.

Prescription Drug Monitoring Program (PDMP)

- Prohibit donations of pharmaceutical manufacturers from being used to support the monitoring program.
- Modify current PDMP data submission requirements from 15 to seven days.
- Establish the Department of Health as the administrative authority for the PDMP in place of the Office of Drug Control.

In addition, the bill as amended would establish an appropriation of \$3 million in non-recurring funds in provided to defray the cost to FDLE and local law enforcement agencies of securing Schedule II and Schedule III controlled substance inventories during the quarantine period, investigate activities and prosecution of crimes related to prescribed controlled substances.

> Representative John Legg Speaker pro tempore Office of Public Information 850.921.7747

PublicInfo@myfloridahouse.gov



Frequently Asked Questions: Distribution of Controlled Substances

What constitutes a controlled substance?

Controlled substances are drugs with potential for abuse and addiction delineated by law in five schedules based on level of risk of addiction and level of medical value.

What are the most frequently abused prescription drugs in Florida? Oxycodone, hydromorphone, hydrocodone and methadone.

What are pain management clinics?

Pain clinics are privately owned clinics, facilities, or offices which advertise the treatment of chronic pain or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substances.

Does the legislation address what legal action will be taken against a practitioner who is found dispensing controlled substances after the ban is implemented?

The proposed legislation classifies the unlawful dispensing of controlled substances as a third degree felony punishable by imprisonment up to five years and fines up to \$5,000.

What if an individual cannot make it to a pharmacy to fill a prescription of a needed controlled substance?

Proponents of the bill emphasize that most doctors presently do not dispense controlled substances or any other kind of drug at their healthcare facility, thus requiring patients to pick up prescriptions at an appropriate pharmacy location. Proponents also assert that while on-site medication dispensing is convenient, the safeguards created for all Floridians through a dual-step prescription and dispensing process outweigh the desire for individual convenience.